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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,049	07/18/2000	Mark D. Yandell	CL000735	9668

7590 09/20/2004

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ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 09/20/2004

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/619,049
Filing Date: July 18, 2000
Appellant(s): YANDELL, MARK D.

Lin-Sun-Hoffman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 7, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 4, 6, 8, 22-26 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(i) Claims 4, 6, 8, 22-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/618,893. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending application comprise SEQ ID Nos. 85-87 which match absolutely with the SEQ ID Nos. 853-855 of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(ii) Claims 4, 6, 8, 22-26 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to isolated nucleotide and polypeptides, comprising a sequence set forth in SEQ ID NO. 853-855.

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the nucleotide sequences (SEQ ID Nos. 853-855). Some of the cited utilities identified by the examiner are to use these nucleic acids as targets for developing insecticidal agents and to identify vertebrate and invertebrate orthologs. These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well-established utilities for the nucleic acids or the underlying polypeptide. No well established utilities for theses specific polypeptide encoding the nucleotide sequences (SEQ ID Nos. 853-855) are identified in either the specification or in the cited prior art.

Given the absence of a well established utility, the final issue is whether substantial and specific utilities are disclosed in the specification. Here, no substantial utilities which are

specific to these nucleotide sequences and polypeptide encoded by these nucleotide sequences are identified. As noted in the utility guidelines, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities. No substantial utility is identified for these specific SEQ ID Nos. 853-855 in the specification. Further, none of the recited utilities in the specification are specific to the SEQ ID Nos. 853-855. None rely on any unique feature of these nucleic acids or polypeptide encoded by SEQ ID NOs. 853-855. Therefore, the instant claims, drawn to isolated nucleotides and encoded polypeptides comprising SEQ ID Nos. 853-855 lack patentable utility.

(11) Response to Argument

Introduction

The instant claims 4, 22-23 are drawn to an isolated nucleic acid consisting of a nucleotide sequence selected from the group consisting of a nucleotide sequence consisting of SEQ ID NO. 854, and 853, that encodes a protein comprising the amino acid sequence of SEQ ID NO. 855 and a nucleic acid molecule that is complementary to SEQ ID Nos. 853-555. Claims 6, 8, 24-26 are drawn to a vector and a host cell comprising the SEQ ID Nos. 853-854. Thus current claims are drawn to specific nucleic acid sequences and an amino acid sequence that encodes the said nucleic acid sequences.

Response to the arguments to the rejection under provisional obviousness-type double-patenting

With respect to the rejection made in the previous office action under provisional obviousness - type double patenting, Appellant' s arguments with respect to claims 4, 6, 8, and 22-26 are considered and are found persuasive. Examiner notes that the co-pending application is

now abandoned and therefore the rejection under provisional obviousness-type double-patenting is withdrawn herein.

Response to the arguments to the rejection under 35 USC 101

The instant specification discloses that the nucleic acid sequences and proteins of the current application are particularly useful in insecticide screening assays, in cell-based or cell-free systems and can be used in assays to determine the biological activity of the protein(s) in high-throughput screening assays, raising antibodies, and as markers for tissues. However, the specification fails to establish any specific or substantial utility to the specific nucleic acid sequences (SEQ ID Nos. 853-855) as claimed in the instant claims. Appellant's assertions on page 6-7 of the appeal brief, regarding the guidelines for the Utility requirement and the assertions regarding the rejection of instant claims under 35 USC 101 are fully considered and not found persuasive.

The starting point for determining whether a nucleic acid molecule selected from the group consisting of SEQ ID NO: 853-855 possesses utility under 35 U.S.C. § 101 Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). As set forth in Brenner, at 534-35, 148 USPQ at 695, the basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until [an invention] is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Special attention must be paid to the Brenner court's statement that a patent should issue only when an invention possesses "substantial utility," i.e., "where a specific benefit exists in

currently available form." Whether a claimed invention is useful under 35 U.S.C. § 101 is a question of fact. Cross v. Iizuka, 753 F.2d 1040, 1044 n.7, 224 USPQ 739, 742 n.7 (Fed. Cir. 1985).

Rather than setting a de minimis standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695.

On page 8 of the appeal brief, Appellant argues that the examiner has not shifted the burden of proof, and directs the attention to the pages 13-14 of the instant specification which states, In addition, the specific subset of genes, transcripts, and proteins are essential for survival; when altered by way of a P-element insertion, it produces a lethal phenotype" . Appellant's arguments are fully considered and the specific statements are found not persuasive, because the claims are drawn to specific nucleic acid sequences (SEQ ID Nos. 853-855) and do not recite whether these sequences are altered by P-element insertion or not and whether these sequences produce a lethal phenotype or not. The utilities as disclosed in the specification are non-specific uses that are applicable to any nucleic acids in general and not particular or specific to the nucleic acids (SEQ ID Nos. 853-855) being claimed." For example, "determining whether the claimed nucleic acids have or do not have a polymorphism (insertion) would require determining whether there was a polymorphism within such a sequence and then determining how to use this information in a patentably meaningful way.

On page 9 of the appeal brief, Appellant argues that the examiner identified credible utilities for the nucleic acids, which are used as targets for developing insecticidal agents and assert that this credible utility is apparent to the person of the ordinary skill in the art and argue that no

evidence was provided to establish facts to the contrary. Appellant's arguments are fully considered and found not persuasive, because the general or non-specific utilities such as screening assays to identify insecticidal agents are not specific to the claimed nucleic acid sequences (SEQ ID Nos. 853-855). The specification fails to identify how this credible utility is specific to the particular sequence claimed (SEQ ID NO. 853-854) or substantial in any particular way, because the utilities as disclosed in the specification are general (non-specific) utilities to a wide range of drosophila G-protein related genes and none of these utilities are specific to the sequences (SEQ ID Nos. 853-855) as claimed in the instant claims. Further as pointed out by the appellants to the statement disclosed in specification on pages13-18 which indicates that these genes are essential for survival; *when altered* by way of a P-element insertion, it produces a lethal phenotype". The instant claims do not recite whether the claimed nucleic acid sequences are altered by p-element insertion or not and also do not recite whether the claimed nucleic acid produces a lethal phenotype or not. Again, the present specification does not attribute any property in terms of trait, or phenotype to any of the nucleotide molecules set forth in SEQ ID NO: 853-855. In the absence of such information, using the claimed molecules to isolate other molecules, which themselves lack substantial utility, does not represent a substantial utility. Thus the specification fails to establish any specific substantial utility to the specific nucleic acid sequences as claimed.

On pages 9-10 of the appeal brief, Appellant argues that these credible utilities as disclosed in the specification are not "throw-away" or "landfill" utilities, and argues that these proteins of the invention are essential to Drosophila survival and these proteins can be used as insecticide agents. Further Appellant asserts that these proteins are particularly useful in

insecticide screening assays, in cell-based or cell-free systems and can be used in assays to determine the biological activity of the protein(s) in high-throughput screening assays, raising antibodies, and as markers for tissues and argues that one of the utilities cited by the examiner is related to use in research and cites MPEP sections 2107-2100-33.

Appellant's assertions are fully considered. Appellant correctly pointed out that one of the three utilities cited by the examiner is used in research as research tools. The MPEP sections 2107-2100-33 also state that "Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. In the instant case, Examiner cited utilities as disclosed in the specification, are asserted utilities that requires further research to identify or reasonably confirm. The asserted utilities include the screening assays used to determine the targets for insecticidal agents, which clearly indicates that these asserted utilities and not specific to the sequences as claimed and require further research to identify or reasonably confirm the real-world utility. In addition, Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a "plastic-like" polypropylene capable of being pressed into a flexible film was held to show that the applicant was "at best ... on the way to discovering a practical utility for polypropylene at the time of the filing," but not yet there. Ziegler, at 1203, 26 USPQ2d at 1605.

Finally, Appellant argues that the PTO has not established burden of proof and cites In re Brana case law and asserts that the PTO has not provided evidence to maintain the rejection

and the rejections are inconsistent with the MPEP guidelines. The Appellant does not distinguish the cited caselaw of In re Brana. This case law is distinguishable from the current situation. The Federal Circuit confirmed in In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The specification disclosed that the claimed compounds had higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442. In the instant case, the instant claims are drawn to specific polynucleotides encoding a protein (SEQ ID Nos. 853-855), which has no identified activity. The function of this gene and its resulting protein are as yet undetermined with no known function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there is no immediately apparent or "real world" utility as of the filing date directly consistent with *Brenner v. Manson*.

Thus the instant claims drawn to specific nucleic acid and protein sequences (SEQ ID Nos. 853-855) do meet the guidelines under 35 USC 101.

Conclusions

For the reasons above the specific nucleic acid sequences and the protein encoded by said nucleic acid sequences as claimed in the instant invention lack utility.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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September 9, 2004

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